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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,902	01/11/2001	Roberts S. David	PC9047D	1327

23913 7590 11/28/2005

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/758,902	DAVID ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response after final filed 1-27-05 has been entered into the record. Claims 1-17 have been canceled and claims 18-20 are pending and under examination.

The finality of the rejection of the last Office action is withdrawn in view of the new grounds of rejection set forth below.

Applicants should note that the examiner in charge of this application has changed. Please address all future correspondence to Exr. Patricia A. Duffy.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § § 1.821-1.825 for the reason(s) set forth below. Full compliance with the sequence rules is required in response to this office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,083,512 in view of Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.) and .

The claims of the patent teach all of the elements of the claimed invention except for the inclusion of a viral immunogen.

Farmers and Consumers Market Bulletin disclose a clostridial vaccine composition which comprises a viral immunogen from influenza, equine viral rhinopneumonitis, strangles and teaches the annual vaccination with the multivalent vaccine reduces the threat of infection from both the bacterium and the virus.

Kensil et al show the use of a saponin adjuvant in association with an antigen, wherein the exemplified vaccine comprises a viral antigen. Kensil establishes the adjuvant activity of saponin is effective for viruses.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to include any of the respiratory viral immunogens of Farmers and Consumers Market Bulletin in the multicomponent Clostridial vaccines of the patent because Kensil et al teach that saponins are effective for adjuvanting a viral

antigen and Farmers and Consumers Market Bulletin disclose the conventional combination of Clostridial vaccine antigens with respiratory viral antigens.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983) in view of Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991).

Seifert teaches the use of a saponin adjuvant in the formulation of a multivalent clostridial vaccine using toxins of apparently different strains of Clostridial pathogens for the purposes of obtaining enhanced protective immune responses in a host. Seifert teach that the group has isolated three local pathogens from anaerobic infections and these pathogens are used for producing the anatoxin. The anatoxin from the three pathogens are toxoided with formalized sodium chloride solution and the toxoids are purified and concentrated. The toxoid vaccine is mixed with anthrax spores in saponin and administered intracutaneously at a dose of 0.2 ml/animal, twice at an interval of 4 weeks. The vaccine provided for a marked protective effect (see page 2). Seifert et al differ by not providing for the addition of antigens from a respiratory virus and multiple serotypes/species.

Geresi et al teach the formulation of multivalent clostridial vaccine compositions Clostridium perfringens antigens (C and D-type toxins: different serotypes) and tetanus toxoid (different species), which also comprise a viral antigen (see page 38).

Farmers and Consumers Market Bulletin disclose a clostridial vaccine composition which comprises a viral immunogen from influenza, equine viral rhinopneumonitis, strangles and teaches the annual vaccination with the multivalent vaccine reduces the threat of infection from both the bacterium and the virus.

Kensil et al show the use of a saponin adjuvant in association with an antigen, wherein the exemplified vaccine comprises a viral antigen. Kensil establishes the adjuvant activity of saponin is effective for viruses.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the Seifert vaccine by adding any desired additional clostridial components as taught by Geresi or Farmers and Consumers Market Bulletin and include a respiratory viral antigen as taught by Farmers and Consumers Market Bulletin because Geresi and Farmers and Consumers Market Bulletin teach that it is conventional to combine the multivalent clostridial vaccine with viral components and both Seifert and Kensil teach the use of saponin as an effective adjuvant for the enhancement of an immune response with either a clostridial or viral antigen respectively the combined vaccine would provide the advantage of reduced time and cost for administering multiple vaccines to farm/ranch animals. Absent unexpected results, one of skill in the art would expect the modified composition to protect from infection because the saponin adjuvant was effective to generate protective immunity in cattle and that similar compositions with different adjuvants were also effective to generate protective immunity.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983), Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) as applied to claims 18 and 20 above further in view of Green et al (The Veterinary Record, 120:435-439, 1987).

The teachings of Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983) in view of Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) as combined are set forth above. The teachings differ by not explicitly combining immunogens from six or more species or serotypes of *Clostridium*.

Green et al teach the formulation of a multi-valent clostridial vaccine for the purposes of stimulating a protective immune response against multiple serotypes and species of this pathogen. Green et al teach three known commercially available vaccines comprising at least 7 different serotypes/species of Clostridium for protection from infection (Tasvax, Heptavac, Covexin) page 435, column 2, Table 1.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to modify the composition as combined *supra* by adding the other known individual clostridial vaccine toxoid components of Green et al (i.e. *C. perfringens* (serotype D), *C. septicum, C. novi, C. haemolyticum and C. chauveoi*) because combined vaccines were commercially available and known to be effective for broad protection for a variety of pathogens in farm animals. Given the demonstrated efficacy and commercial availability of the 7- and 8- way combination vaccines, the combination as combined would be expected to be effective to protect from infection.

Status of the Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy, Ph.D.
Primary Examiner
Art Unit 1645